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| EXAMINER | |
|---|---|
| BAUM, STUART F | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) |
|---|---|---|
| | 10/574,470 | TAKAGI ET AL. |
| | Examiner | Art Unit |
| | STUART BAUM | 1638 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *3/28/2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *2,5-8,16,17,21-24,26,28-32,35 and 36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-4, 9-15, 18-20, 25, 27 and 33-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 March 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/31/06, 9/22/06, 11/17/07, 8/21/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**DETAILED ACTION**

1. Claims 1-36 are pending.

2. Applicant's election with traverse of Group I, claims 1, 3-4 and 9-34, including SEQ ID NO:137 and 136 and the peptide sequence of SEQ ID NO:17 in the reply filed on 3/28/2011 is acknowledged. The traversal is on the ground(s) that the Hiratsu et al does not teach or suggest that the protein with an amino acid sequence represented by SEQ ID NO:136 serves as a transcription factor that promotes transcription of a gene associated with anther dehiscence or a plant with suppressed anther dehiscence produced by a chimeric protein as set forth in claim 18 (page 16 of Response, bottom paragraph and top paragraph of page 17). Applicants contend peptides that convert arbitrary transcription factors into transcription repressors are known and can be used in the invention (page 17 of Response, 2nd full paragraph).

This is not found persuasive because the Office contends the special technical feature of the application is recited in the first claim which is drawn to a peptide sequence that converts a transcription factor into a transcriptional repressor, which is taught in the prior art as stated in the restriction requirement mailed 2/24/2011. Applicants' chemical compounds, i.e., different DNA sequences encoding different polypeptides or different peptide sequences, each have different properties and different core structures that elicit different activities. The Office notes that while Applicants have listed a few peptide sequences that have the ability to convert a transcription factor into a transcriptional repressor, a common core structure associated with the particular function is not known.

The requirement is still deemed proper and is therefore made FINAL.

Claims 2, 5-8, 16-17, 21-24, 26, 28-32 and 35-36 are withdrawn from consideration for being drawn to non-elected inventions.

3. Claims 1, 3-4, 9-15, 18-20, 25, 27 and 33-34, including SEQ ID NO:137 encoding SEQ ID NO:136 and SEQ ID NO:17 are examined in the present office action.

***Oath and Declaration***

4. The Oath and Declaration is objected to because Applicants claim as a Foreign Priority Document application 2004-002191 instead of 2004-002192.

***Claim Objection***

5. Applicant is advised that should claim 10 be found allowable, claims 12 and 14 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 27 is objected to for being drawn to non-elected inventions. Correction is requested.

Claim 34 is objected to for being an improper form of a Markush Group, i.e., "includes at least one of a group consisting of:" instead of –selected from the group consisting of:--.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 3-4, 9-15, 18-20, 25, 27 and 33-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection includes dependent claims.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Claim 1 is indefinite for reciting "causing a plant to produce a chimeric protein". It is unclear how a plant can produce a chimeric protein.

Claim 1 is indefinite for reciting "arbitrary transcription factor". Applicants have not set forth the metes and bounds of an "arbitrary transcription factor".

In claims 3-4, 9-15, 18-20, 27 and 34, line 1, "A" should be amended to --The-- for proper antecedence.

Claim 9 recites the limitation "the transcription factor associated with formation of stamen and pistil" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 25 provides for the use of a gene, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 25 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e.,

results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Written Description***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 3-4, 9-15, 18-20, 25, 27 and 33-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method of producing a sterile plant comprising causing a plant to produce a chimeric protein in which a transcription factor that promotes expression of a gene associated with formation of floral organs is fused with a functional peptide that converts an arbitrary transcription factor into a transcription repressor, thereby sterilize the plant, or wherein the transcription factor is associated with stamen or pistil formation, or wherein stamen formation is suppressed, or wherein a double-flowered plant is produced, or wherein the plant is transformed with an expression vector comprising a coding gene of the transcription factor and a polynucleotide that encodes a functional peptide, or wherein the transcription factor is a protein

with an amino acid sequence represented by SEQ ID NO:136 or a protein with the substitution, deletion, insertion and/or addition in the amino acid sequence represented by SEQ ID NO:136 and capable of promoting transcription of a gene associated with dehiscence of anther, or wherein the transcription factor exhibits at least 50% homology with SEQ ID NO:136, or wherein the transcription factor has a base sequence of SEQ ID NO:137 or the gene hybridizes under stringent conditions with SEQ ID NO:137; or a plant produced by said method.

Because Applicants do not define the term "represent", the Office defines the term according to the Merriam Webster Online Dictionary, which defines "represent" to mean: to serve as a specimen, example or instance of, (Merriam Webster Online Dictionary. 2008, www.m-w.com/home.html; a copy of the definition is enclosed). Therefore, the office interprets this to read on more than just a single protein or nucleic acid sequence.

Applicants disclose the nucleic acid sequence of the NACAD1 of SEQ ID NO:137 and the encoded protein as SEQ ID NO:136 (pages 32-33). Applicants disclose SEQ ID NO:17 (sequence listing).

The Applicants do not identify essential regions of any transcription factor that promotes expression of a gene associated with formation of floral organs or essential regions of a functional peptide that converts an arbitrary transcription factor into a transcriptional repressor, nor do Applicants describe any polynucleotide sequences that encode a transcription factor that exhibits 50% homology to SEQ ID NO:136 and that encode a functional protein.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court

stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of polynucleotide sequences encoding a protein falling within the scope of the claimed genus of polynucleotides that encode any transcription factor that promotes expression of a gene associated with formation of floral organs or a representative number of polynucleotide sequences encoding a functional peptide that converts an arbitrary transcription factor into a transcriptional repressor or a representative number of polynucleotide sequences that encode a protein with the substitution, deletion, insertion and/or addition in the amino acid sequence represented by SEQ ID NO:136. Applicants only describe a single sequence of SEQ ID NO:137. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for the claimed transcription factor and functional peptide, it remains unclear what features identify said polypeptides. Both the prior art and the specification fail to disclose a correlation between the

structure of the claimed sequences and the recited function. Since said genus has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims.

***Scope of Enablement***

8. Claims 1, 3-4, 9-15, 18-20, 25, 27 and 33-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for producing a sterile plant comprising transforming a plant with an expression cassette comprising a nucleic acid sequence of SEQ ID NO:137 operably linked to SEQ ID NO:17 and plant transformed therewith, does not reasonably provide enablement for said method comprising nucleic acid sequences exhibiting less than 100% identity to SEQ ID NO:137 and SEQ ID NO:17 or a nucleic acid encoding a protein exhibiting less than 100% identity to SEQ ID NO:136 or wherein the method comprises the step of "causing a plant to produce a chimeric protein in which a transcription factor that promotes expression of a gene associated with formation of floral organs is fused with a functional peptide that converts an arbitrary transcription factor into a transcription repressor". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by

one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to a method of producing a sterile plant comprising causing a plant to produce a chimeric protein in which a transcription factor that promotes expression of a gene associated with formation of floral organs is fused with a functional peptide that converts an arbitrary transcription factor into a transcription repressor, thereby sterilize the plant, or wherein the transcription factor is associated with stamen or pistil formation, or wherein stamen formation is suppressed, or wherein a double-flowered plant is produced, or wherein the plant is transformed with an expression vector comprising a coding gene of the transcription factor and a polynucleotide that encodes a functional peptide, or wherein the transcription factor is a protein with an amino acid sequence represented by SEQ ID NO:136 or a protein with the substitution, deletion, insertion and/or addition in the amino acid sequence represented by SEQ ID NO:136 and capable of promoting transcription of a gene associated with dehiscence of anther, or wherein the transcription factor exhibits at least 50% homology with SEQ ID NO:136, or wherein the transcription factor has a base sequence of SEQ ID NO:137 or the gene hybridizes under stringent conditions with SEQ ID NO:137; or a plant produced by said method.

Applicants disclose the nucleic acid sequence of the NACAD1 of SEQ ID NO:137 and the encoded protein as SEQ ID NO:136 (pages 32-33). Applicants disclose SEQ ID NO:17 (sequence listing). Applicants disclose the construction of an expression cassette comprising the

nucleic acid sequence of SEQ ID NO:137 operably linked to SEQ ID NO:17 and plant transformed therewith, wherein the transformed plant exhibits anthers in which dehiscence does not occur (pages 79-85).

Applicants have not reduced to practice the full scope of their broadly claimed invention. Applicants have not provided any teachings for one skilled in the art to predict and isolate nucleic acid sequences that encode a protein with the necessary activity to be operable in Applicants' invention. Applicants have not taught which regions of the respective polynucleotides can be used to amplify any of said polynucleotides or which regions can be used as a probe to isolate any of said polynucleotide sequences. In addition, the instant specification fails to provide guidance for which amino acids of the protein encoded by SEQ ID NO:137 can be altered, the type of alteration, and which amino acids must not be changed, to maintain activity of the encoded protein. The specification also fails to provide guidance for which amino acids can be deleted and which regions of the protein can tolerate insertions and still produce a functional protein.

The state-of-the-art is such that one of skill in the art cannot predict which nucleic acids that a protein with 50% homology to the amino acid sequence of SEQ ID NO:136 will encode a protein with the same activity as a protein encoded by SEQ ID NO:137. The prediction of protein structure from sequence data and, in turn, utilizing predicted structural determinations to ascertain functional aspects of the protein, is extremely complex, and the positions within the protein's sequence where amino acid substitutions can be made with a reasonable expectation of maintaining function are limited (Bowie et al, Science 247:1306-1310, 1990, see especially page 1306). Proteins may be sensitive to alterations in even a single amino acid in a sequence. For

example, the replacement of a glycine residue located within the START domain of either the PHABULOSA or PHAVOLUTA protein receptor with either an alanine or aspartic acid residue, alters the sterol/lipid binding domain (McConnell et al, Nature 411 (6838):709-713, 2001, see especially page 710, left column, 2nd paragraph).

Re: claim 9 recites that the sterile flower exhibits a double flower but Applicants have not taught that any arbitrary transcription factor when fused with any functional peptide can produce said phenotype.

Re: claim 25 is drawn to a producing process of a sterile plant comprising any of the listed sequences but none of the sequences include the peptide sequence of SEQ ID NO:17 to convert the protein into a dominant negative, which is the basis of the claimed invention.

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, either by using non-disclosed fragments of SEQ ID NO:137 as probes or by designing primers to undisclosed regions of SEQ ID NO:136 and isolating or amplifying fragments, subcloning the fragments, isolating without guidance a peptide sequence that turns a transcription factor into a transcriptional repressor, producing expression vectors and transforming plants therewith, in order to identify those, if any, that when over-expressed produce a plant in which the transcription factor has become a transcriptional repressor and the plant is sterile.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 10-15, 18, 20, 25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hiratsu et al (2003, The Plant Journal 34:733-739; listed in IDS) taken with Steiner-Lange et al (2003, The Plant Journal 34:519-528; listed in IDS).

The claims are drawn to a method of producing a sterile plant comprising causing a plant to produce a chimeric protein in which a transcription factor that promotes expression of a gene associated with formation of floral organs is fused with a functional peptide that converts an arbitrary transcription factor into a transcription repressor, thereby sterilize the plant wherein the plant is transformed with an expression vector comprising a coding gene of the transcription factor and a polynucleotide that encodes the functional peptide, or wherein the transcription factor is a protein with an amino acid sequence represented by SEQ ID NO:136 or a protein with the substitution, deletion, insertion and/or addition in the amino acid sequence represented by SEQ ID NO:136, or wherein the gene hybridizes under stringent conditions with a sequence represented by SEQ ID NO:137 and capable of promoting transcription of a gene associated with dehiscence of anther, or wherein the functional peptide has an amino acid sequence of SEQ ID NO:17.

Because Applicants do not define the term "represent", the Office defines the term according to the Merriam Webster Online Dictionary, which defines "represent" to mean: to serve as a specimen, example or instance of, (Merriam Webster Online Dictionary. 2008, www.m-w.com/home.html; a copy of the definition is enclosed). Because Applicants recite an amino acid sequence "represented" by SEQ ID NO:136, the office interprets this to read on more than just a single protein sequence.

The Office interprets the recitation "a protein with the substitution, deletion, insertion and/or addition in the amino acid sequence represented by SEQ ID NO:136" to read on a large number of protein sequences.

Hiratsu et al disclose recombinant constructs comprising a nucleic acid molecule encoding a transcription factor operably linked to a nucleic acid encoding the EAR-motif, a repression domain of only 12 amino acids that acts to convert the linked transcription factors to dominant repressors (abstract and page 738, right column, "Cloning and transformation"). Hiratsu et al disclose the EAR-motif comprises amino acids LDLDLELRLGFA, which is the same sequence as Applicants' SEQ ID NO:17. Hiratsu et al state "We used the CaMV 35S promoter to drive the chimeric genes and succeeded in obtaining dominant-negative phenotypes using four transcription factors" (page 738, left column, bottom paragraph).

Hiratsu et al teach that the disclosed system is useable as a gene silencing technique and has advantages over existing silencing methods, i.e., it is unusually simple and it can induce a dominant-negative phenotype with high efficiency (paragraph bridging the left and right columns on page 738, and the 1st full paragraph on the right column on page 738). Lastly, Hiratsu et al

teach that this system of using the EAR-motif to create dominant-negative mutants is useful for the manipulation of plant traits in agricultural biotechnology.

Hiratsu et al do not disclose a method for producing a sterile plant comprising transforming a plant with a recombinant expression vector comprising a coding gene of a transcription factor fused with a polynucleotide that encodes a peptide that converts a transcription factor into a transcription repressor and a transcription factor involved in dehiscence of anthers.

Steiner-Lange et al disclose the identification and cloning of a gene from Arabidopsis, AtMYB26, that when mutant results in a plant having a defect in anther dehiscence (entire document). Steiner-Lange et al state "Male sterile plants are useful tools for hybrid seed production (page 526, left column, top paragraph).

Given the recognition of those of ordinary skill in the art of the value of producing a male sterile plant as taught by Steiner-Lange et al, one of ordinary skill in the art would be motivated to produce a sterile plant by combining the teachings of Hiratsu et al of using the EAR-motif to produce a dominant-negative transcription factor with the teachings of Steiner-Lange et al of disrupting the expression of AtMYB26 that results in a male sterile plant. Given the Office's interpretation of the claims as discussed above and given the teachings of Hiratsu et al that supply the motivation for using the EAR-motif to produce a dominant negative transcription factor, as discussed above, one of ordinary skill would be apprised of all the necessary information to produce a method of producing a sterile plant as recited in the claims.

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Stuart F. Baum/
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Art Unit 1638